

## Pfizer anti-smoking drug has heart risks: US

## June 16 2011

US regulators said Thursday that the label on Pfizer's anti-smoking drug Chantix must be changed to warn of a slightly higher risk of heart problems in patients who already have cardiovascular disease.

The drug, also known as varenicline, was shown in a clinical trial of 700 smokers to be associated with an elevated risk of heart attack, angina, and <u>clogged arteries</u> in some patients when compared to a placebo.

"The prescribing information for this drug product will be strengthened to inform the public that use of varenicline may be associated with a small, increased risk of certain cardiovascular adverse events in patients who have cardiovascular disease," the <u>Food and Drug Administration</u> said.

FDA has ordered the drug-maker to "conduct a large, combined analysis (meta-analysis) of randomized, placebo-controlled trials" and will update the public once that is complete.

Earlier this year, some 1,200 plaintiffs in the United States who claim Chantix causes depression or <u>suicidal thoughts</u> filed lawsuits against Pfizer.

The drug is approved in almost 90 countries around the world and used by some seven million Americans.

If Chantix is found to be dangerous it could be withdrawn from the US market, where sales have suffered since alleged links to depression and



suicide mushroomed last year.

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